EXHIBIT 25

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL a corporation of Barbados,	)	
Plaintiff,	)	C.A. No. 05-586-GMS
	)	C.A. No. 05-730-GMS
v.	)	C.A. No. 06-620-GMS
	)	CONSOLIDATED
ANDRX PHARMACEUTICALS, LLC and ANDRX CORPORATION	)	
Defendants.	)	

DECLARATION OF PROFESSOR ROLAND BODMEIER, Ph.D.
IN SUPPORT OF ANDRX'S ANSWERING CLAIM CONSTRUCTION BRIEF

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Attorneys for Defendants Andrx Pharmaceuticals, LLC and Andrx Corporation

Dated: April 24, 2007
784479 / 30015

I. INTRODUCTION

1. I am a Professor of Pharmaceutics at the College of Pharmacy at the Freie Universität Berlin in Berlin, Germany.

2. Prior to joining the faculty at the Freie Universität Berlin in 1994, I was a tenured Associate Professor of Pharmaceutics in the College of Pharmacy at the University of Texas at Austin, and I still serve as an adjunct Professor of Pharmaceutics at the University of Texas at Austin. I also served as a visiting Professor of Pharmaceutics at the University of Nancy in Nancy, France from 1994-1996.

3. I received a B.S. in Pharmacy from the Ludwig-Maximilians Universität in Munich, Germany in 1982, a Ph.D. in Pharmaceutics from the University of Texas at Austin in 1986 and a Dr. rer.nat.habil. degree (an additional doctorate degree after the Ph.D., which qualifies for a professorship in Germany) from the Universität Regensburg in Regensburg, Germany in 1993.

4. I have lectured, researched and written extensively in the field of injectable and oral drug dosage form design and drug delivery systems, including: biodegradable polymers, controlled release drug delivery systems, especially biodegradable injectable microspheres, implants and in situ systems, effective delivery of poorly water-soluble drugs, optimization of drug release properties of dosage forms and identification and optimization of appropriate process and formulation parameters in the preparation of dosage forms.

5. I am the author of approximately 130 refereed papers, 8 book chapters, and 7 review papers.

6. I am currently an associate editor of the European Journal of Pharmaceutical Sciences and a member of the editorial boards of the following peer reviewed journals: "Drug Development and Industrial Pharmacy", "European Journal of Pharmaceutics and Biopharmaceutics" and the "Journal of Microencapsulation". I am also a reviewer for numerous journals in the field, including "Pharmaceutical Research", "Journal of Pharmaceutical Sciences", "Journal of Controlled Release" and "International Journal of Pharmaceutics".

7. I am a frequent grant reviewer for national and international public research organizations including the major German Research Association, the "Deutsche Forschungsgemeinschaft" and European programs.

8. I am named as an inventor on more than twenty-five (25) patents and pending patent applications in the field of drug delivery systems.

9. I am a member of several professional societies, including the Controlled Release Society, the American Association of Pharmaceutical Scientists and the Arbeitsgemeinschaft Pharmazeutischer Verfahrenstechnik.

10. I have received several awards, including the Parenteral Drug Association Award and the Merck Young Investigator Award.

11. I have supervised approximately 25 undergraduate researchers, 7 postdoctoral research fellows, 15 visiting scientists and the dissertations of 31 Ph.D. and 3 M.S. students. I currently supervise a research group consisting of 13 Ph.D. students.

12. My primary area of expertise and the focus of my research are in the field of controlled release drug delivery systems. Over the course of the more than 20-years that I have worked in this field, I have gained extensive knowledge and understanding of drug delivery systems and formulations.

13. I have consulted for and conducted many presentations and workshops in these fields for pharmaceutical companies and at pharmaceutical conferences.

14. A more detailed description of my background and qualifications can be found in my curriculum vitae, which is attached as Exhibit A.

15. I have reviewed Biovail's United States Patent No. 5,529,791 ("the '791 patent"), the prosecution history of the '791 patent, as well as many documents and materials regarding Biovail's products and Andrx's proposed tablet products which are the subject of this lawsuit. I have attached a copy of the '791 patent as Exhibit B. I have previously submitted expert reports in this case regarding validity and infringement of the '791 patent, attached as Exhibits C and D, respectively. I have also reviewed Biovail's Opening Claim Construction Brief, and the

Declaration of Gerald S. Brenner, Ph.D. in Support of Biovail's Opening Claim Construction Brief.

16. I submit this declaration in support of Andrx's Answering Claim Construction Brief to address several statements contained in Dr. Brenner's Declaration.

II. THE GENERAL TUTORIAL AND DISCUSSION OF THE '791 PATENT

17. I note that Dr. Brenner provides what is termed as "a general tutorial" on the absorption of drugs from extended-release oral dosage forms.

18. In that tutorial, he mentions three distinct stages in the process of the absorption of drugs into the body. In the first stage, the drug is solubilized, or brought into solution. In the second phase, the solubilized drug passes across a membrane, or is released from the oral dosage form. And the third, final, phase is the absorption of the drug into the body. (Brenner Decl., ¶¶ 12-13.) Dr. Brenner notes that the absorption process can be problematic if "the drug dissolves too slowly, or if the drug once dissolved comes out of solution." (*Id.* at ¶ 14.) Dr. Brenner states that a formulator might address either of these issues using a "wetting agent." (*Id.* at ¶ 15.) Dr. Brenner states that "[w]etting agents can be added to these types of dosage forms to aid in the dissolution of the drug, and/or to maintain the drug in a dissolved state." (*Id.* at ¶ 14.)

19. I agree with Dr. Brenner as a general matter that these are three distinct stages in the absorption of drugs into the body from solid, oral dosage forms. They can best be summarized as dissolution, release, and absorption. Dr. Brenner, however, provides no analysis as to whether and how these processes affect one another, apart from suggesting that unspecified "problems can develop" in the third stage if the drug is slow-dissolving or precipitates from solution in the first stage. (Brenner Decl., at ¶ 14.)

20. Similarly, the '791 patent provides no teaching or guidance relating to these three distinct stages in the absorption of diltiazem in the body. Rather, the claims of the '791 patent expressly tie the action of the wetting agent to the first stage of the process: "to maintain[ing] the solubility of the Diltiazem in each bead" and "ensuring that the solubility of the Diltiazem is unaffected by the pH of the gastrointestinal tract or other adverse conditions the composition will

meet therein. . . ." (Ex. B, at 8:65-9:2.) The file history reinforces this claim language by pointing to the wetting agent's control over the solubility of diltiazem: "The wetting agents claimed in the present invention are substances which are believed to modify the solubility of Diltiazem inside the coated beads when they are placed in a dissolution medium or when they are ingested by a mammal." (Ex. F, p. 13.) Thus, it is my opinion that the actions of the wetting agent are required to occur in the first stage of the process – the solubilization stage – and not in the latter stages, the release or the absorption stages.

21. Dr. Brenner, however, appears to go further than this in his declaration. He states that "[w]ithout the admixture, solid diltiazem particles could form resulting in lower bioavailability (less amounts of drug to the patient) and disruption of the gradual release of the drug into the bloodstream." (Brenner Decl., at ¶ 30.) I note that both of the potential problems identified by Dr. Brenner have to do with the final two stages of the absorption process – release and absorption – and not with the first stage of the absorption process – solubilization. Since the patent claims specifically tie the action of wetting agent only to the first stage, solubilization, I believe Dr. Brenner is incorrect in pointing to problems that may arise in the second two stages as problems solved by use of a wetting agent in admixture with diltiazem salt.

22. Furthermore, simply measuring release rates (through *in vitro* dissolution experiments) or bioavailability (through *in vivo* blood plasma concentration testing) does not tell a person of skill in the art what affect (if any) a wetting agent has on the ***solubility*** of a particular ingredient. The three stages Dr. Brenner mentions are each a highly complex process that includes numerous variables. Attributing differences in release or blood plasma concentrations solely to the presence or absence of one particular component's effect on the *in vivo* solubility of another component in an oral dosage form is beyond the current capabilities of pharmaceutical science.

23. I further disagree with another aspect of Dr. Brenner's description of the '791 patent, where Dr. Brenner states that "as the diltiazem hydrochloride salt goes from an acid environment to a less acidic environment, for example, from the acidic environment of the

stomach to the less acidic environment of the intestine, it becomes less soluble and solid particles of diltiazem can precipitate." (Brenner Decl., at ¶ 25.) He goes on to add "[s]uch precipitation is undesirable because it results in a loss of the amount of therapeutically effective diltiazem available to the body." (*Id.*) Dr. Brenner further states that it is important in extended-release formulations "to make sure that the formulation avoids the potential for the diltiazem to precipitate out – ***from solution*** – during the *in vivo* transit of the drug through the gastrointestinal tract." (Brenner Decl., at ¶ 26 (emphasis in original).)

24. Based on the solubility values of diltiazem and diltiazem hydrochloride, I disagree that precipitation from solution is a problem with extended-release diltiazem solid oral dosage forms, especially in view of the small amount of diltiazem delivered to the patient's gastrointestinal tract by the oral dosage form over an extended period of time compared to the large volume of fluid present in the patient's gastrointestinal tract. Indeed, diltiazem itself (based on the measured solubility of diltiazem) has a solubility value such that it would be highly unlikely that diltiazem would precipitate out of solution in the gastrointestinal tract. Thus, it is not clear to me why Dr. Brenner emphasizes this point so heavily.

25. Moreover, the '791 patent and its prosecution history make clear that beads are formed from an admixture of wetting agent and diltiazem salt. It is unclear how the importance of this dry state admixture in a bead would preclude precipitation of diltiazem base anywhere in the gastrointestinal tract, as Dr. Brenner is suggesting.

III. THE DEBREGEAS REFERENCE

26. Dr. Brenner provides statements relating to a particular passage from the prosecution history of the '791 patent in which a particular prior art reference is distinguished. That reference is United States Patent No. 4,960,596, issued to Debregeas *et al.* I will refer to that reference as "the Debregeas reference" throughout this declaration. I have attached a copy of the Debregeas reference as Exhibit E.

27. The passage in question comes from an Amendment of June, 1992, attached as Exhibit F, and reads as follows:

> Further, at column 3, lines 4 and 10, Debregeas et al describes the composition of the neutral core of saccharose and fructose to start the building-up process with the binder being polyvinylpyrrolidone to make the different layers of product. By contrast, the present invention does not use the building-up process and this does not make use of a neutral core of saccharose and fructose. Further, Debregeas does not disclose saccharose as a wetting agent. The saccharose contained in the central core of the bead cannot act as a wetting agent because in order to do so the saccharose must be mixed with the diltiazem and, therefore, saccharose must be in solution with Diltiazem. Unfortunately, in this system saccharose can only end up in solution after all the layers of Diltiazem are dissolved. In other words, saccharose can only become effective when there is not [sic – no] longer a need therefor [sic].

(Exhibit F, p. 13.)

28. Dr. Brenner reproduces a portion of this passage in his Declaration, and discusses the excerpt at paragraph 35, as follows:

> 35. According to the '791 inventors, the sequence of events of the Debregeas formulations *in vivo* is that first the membrane would be disrupted, followed by exposure of the drug layer to the aqueous environment. Finally, after the drug layer is dissolved and enters the gastrointestinal tract, the sugar core is then exposed to the aqueous environment and dissolves. Thus, the wetting agent (*i.e.*, sugar) never has the opportunity to form an admixture in the bead (*i.e.*, within the non-ruptured membrane) prior to the drug entering the gastrointestinal tract and being exposed to its less acidic environment.

(Brenner Decl., at ¶ 35.)

29. ***First***, I note that the cited passage from the prosecution history makes no reference whatsoever to the various coatings disclosed in the Debregeas reference. Thus, while Dr. Brenner attributes his rationale to the inventors of the '791 patent, there is no evidence at all in the prosecution history that the inventors ever told the patent office that this behavior was in any way related to the membrane or coating of the various Debregeas formulations. Had the inventors attributed this behavior to the membrane of the Debregeas formulations, as opposed to the structure of the core of the Debregeas formulations, it is my opinion that the inventors would have mentioned the membrane in connection with this statement. They did not. Indeed, the only

distinction drawn by the inventors in the June, 1992 amendment with respect to Debregeas formulations' membranes had to do with the use of organic solvents in applying the Debregeas membranes. (Ex. F, pp. 12-13.)

30. ***Second***, Dr. Brenner states that the Debregeas formulations' membranes would be "disrupted," and "ruptured," giving rise to a release of diltiazem before the wetting agent (the sugar in the Debregeas bead's central core) before an admixture could form. It is not clear what Dr. Brenner is proposing here. His stated analysis suggests that he is referring to one or more large ruptures in the membrane. If this were the case, then a person of ordinary skill in the art would have expected to observe a "dose dump" wherein significant amounts of diltiazem are released quickly. This is directly contrary to what the Debregeas reference describes and claims, however. The Debregeas reference describes and claims "A slow release acid-free Galenical preparation of pharmaceutically acceptable Diltiazem. . . ." (Ex. E, at 8:25-26.) In fact, the Debregeas reference discloses and claims a release of diltiazem from the claimed formulation using United States Pharmacopoeia ("USP") method 21 under the following schedule:

(a) between 5% and 35% after one hour;
(b) between 15% and 40% after two hours;
(c) between 20% and 50% after three hours;
(d) between 30% and 75% after four hours;
(e) between 40% and 80% after six hours;
(f) between 55% and 95% after eight hours;

(Ex. E, at 2:65-3:2, 8:35-40.) Thus, the Debregeas reference is inconsistent on its face with the analysis provided by Dr. Brenner.

31. ***Third***, Dr. Brenner apparently only focuses on one single embodiment in the Debregeas reference – that of the 70 parts shellac and 30 parts ethylcellulose formulation.[1] (Brenner Decl., at ¶ 36.) The Debregeas reference disclosure is not so limited. For example, the Debregeas reference teaches:

[1] The Debregeas reference shellac and ethylcellulose coating also contains talc. (Ex. E, at 3:49-51.)

> Numerous types of coatings may be used to make an outer membrane in accordance with the invention. According to the invention, such coatings should be considered as being equivalent providing they make it possible to obtain products which are biologically equivalent to those described below by way of non-limiting example, with bio-availability results being given below for products corresponding to said examples in order to make it possible for the person skilled in the art to appraise said biological equivalence.

(Ex. E, at 3:22-31.) The Debregeas reference also teaches that "[t]he outer membrane of the products in Table IV has the advantage of providing formulations in which the release of Diltiazem is insensitive to pH. . .", and that "equivalent results can be obtained by using other excipients such as a suspension of ETHOCEL AQ sold by Colorcon, EUDRAGIT RL and RS or their equivalents sold by Rohm & Haas. . . ." (Ex. E, at 7:22-28.)

32. Moreover, in addition to these general passages, the Debregeas reference also discusses "a second series" of experiments, wherein "the main ingredient of the outer membrane was a mixture of Aquacoat ECD 30 (an aqueous dispersion of ethylcellulose) and dibutylsebacate." (Ex. E, at 5:44-46.) The Debregeas reference provides *in vitro* dissolution testing results and *in vivo* testing results for these alternatively-coated formulations. (Ex. E, Figs. 2, 9, and 10.) The Debregeas reference provides, in Table IV, a summary of the results for both shellac and Aquacoat based coating formulations. (Ex. E, at 7:3-22 (Table IV).) These results demonstrate that both shellac and Aquacoat based formulations provide slow-release formulations, with a T_{max} value of 4.2 hours (shellac-based formulation), and a range of T_{max} values of 3.0 to 5.6 hours for Aquacoat-based formulations. Dr. Brenner does not specifically analyze that second coating in his declaration,[2] and does not even address the general disclosures contained in the Debregeas reference. Thus, Dr. Brenner's analysis of the Debregeas reference is incomplete, at best.

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[2] Dr. Brenner acknowledges the second type of coating in his declaration at paragraph 33, but provides no analysis relating to it, as he did with respect to the first type. (See Brenner Decl., at ¶ 36.)

33. ***Fourth***, it appears that Dr. Brenner refers to only one of the Debregeas reference coatings as a means to further distinguish the claimed invention over and above whatever the inventors represented to the patent office at the time. However, it is my opinion that the shellac/ethylcellulose coating described in the Debregeas reference is within the scope of claim 1 of the '791 patent. Claim 1 of the '791 patent merely requires that the microporous membrane "compris[e] at least a water-soluble or water-dispersible polymer or co-polymer, and a water-, acid- and base-insoluble polymer and a pharmaceutically-acceptable adjuvant. . . ." (Ex. B, at 9:2-6.) In my opinion, (1) shellac is a water-dispersible polymer or co-polymer, (2) ethyl cellulose is a water-, acid- and base-insoluble polymer, and (3) talc (also used in the Debregeas reference) is a pharmaceutically-acceptable adjuvant. Thus, I believe that Dr. Brenner's attempt to further distinguish the Debregeas reference from the claimed compositions based on one type (of the many types) of coating disclosed in the Debregeas reference is simply incorrect.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

April 20, 2007
Dated

Prof. Roland Bodmeier, Ph.D

TAB A

Curriculum Vitae - Prof. Dr. Roland Bodmeier

PERSONAL

born in Munich, Germany on 4/25/1957; married, two children.

EDUCATIONAL QUALIFICATIONS

Universität Regensburg, Germany	Habilitation	1/1993
The University of Texas at Austin, USA	Ph.D. (Pharmaceutics)	12/1986
Ludwig-Maximilians Universität, Munich, Germany	B.S. (Pharmacy)	7/1982

WORK EXPERIENCE

Institut für Pharmazie Freie Universität Berlin, Germany	Full Professor (C4)	6/1994 – present
College of Pharmacy, The University of Texas at Austin, USA	Associate Professor (tenured)	9/1991 - 5/1994
- " -	Assistant Professor	9/1986 - 8/1991
- " -	Teaching and Research Assistant	8/1982 - 8/1986
Synthelabo-L.E.R.S., Paris, France	Research Assistant	6/1985 - 8/1985

ADJUNCT AND VISITING PROFESSOR POSITIONS

- The University of Texas at Austin (USA, 1994 - present)
- University of Nancy (France, 1994 - 1996)
- The Upjohn Company (USA, 1991)

RESEARCH INTERESTS

- Controlled drug delivery systems:
  - oral drug delivery
  - microencapsulation
  - multiparticulate drug delivery systems
  - coating technology
  - biodegradable and nondegradable polymeric and lipidic carriers
  - drug-carrier complexes
- Delivery systems for peptide/protein drugs
- Solubilization of poorly water-soluble drugs

EDITORIAL POSITIONS

- Associate Editor (1/2004 – present) European Journal of Pharmaceutical Sciences
- Associate Editor (4/1994 – 12/2000) - European Journal of Pharmaceutics and Biopharmaceutics
- Associate Editor (1/1993 - 6/1994) - S.T.P. Pharma Sciences
- Editorial Board (1/2001 - present) - Drug Development and Industrial Pharmacy
- Editorial Board (1/2001 - present) - European Journal of Pharmaceutics and Biopharmaceutics
- Editorial Board (1/1996 - present) - Journal of Microencapsulation
- Editorial Board (6/2003 – present) - Encyclopedia of Pharmaceutical Technology

REFEREE FOR SCIENTIFIC JOURNALS

Archiv der Pharmazie, Biochimica et Biophysica Acta, Carbohydrate Polymers, European Journal of Pharmaceutical Sciences, European Journal of Pharmaceutics and Biopharmaceutics, Industrial and Engineering Chemistry Research, International Journal of Pharmaceutics, Journal of Controlled Release, Journal of Macromolecular Science-Pure and Applied Chemistry, Journal of Microencapsulation, Journal of Pharmaceutical Sciences, Pharmaceutical Development and Technology, Pharmaceutical Research, Planta Medica, Powder Technology, S.T.P. Pharma Sciences

MISCELLANEOUS REFEREE ACTIVITIES

- referee for dissertations and habilitations in Germany, France and Switzerland
- referee for chaired professorships in Germany, England, France and Ireland
- referee for grant applications to national and international public research organisations (DFG, BMBF, EU-programs)
- expert witness in various patent cases (Germany and USA)

SCIENTIFIC ADVISORY BOARD

- Bertex Pharma GmbH, Berlin, Germany (scientific founder)
- Biovector Therapeutics SA, Toulouse, France
- Ellipse Pharmaceuticals, Bordeaux, France

AWARDS

- Parenteral Drug Association Research Award (1988)
- Merck Sharp & Dohme Faculty Development Award (1988)
- Eckerd Fellowship (1991 - 1994)

MEMBERSHIP IN PROFESSIONAL ORGANISATIONS

- Arbeitsgemeinschaft pharmazeutischer Verfahrenstechnik (APV)
- American Association of Pharmaceutical Scientists (AAPS)
- Controlled Release Society (CRS)
- Deutsche Pharmazeutische Gesellschaft (DPhG)

PUBLICATIONS:

1. J.W. McGinity, Chi-Tze Ku, R. Bodmeier, M. Harris: Dissolution and Uniformity Properties of Ordered Mixes of Micronized Griseofulvin and a Directly Compressible Excipient, Drug Development and Industrial Pharmacy, 11(4), 891-900 (1985).

2. R. Bodmeier, J.W. McGinity: Polylactic Acid Microspheres Containing Quinidine Base and Quinidine Sulfate Prepared by the Solvent Evaporation Technique: I. Methods and Morphology, Journal of Microencapsulation, 4(4), 279-288 (1987).

3. R. Bodmeier, J.W. McGinity: Polylactic Acid Microspheres Containing Quinidine Base and Quinidine Sulfate Prepared by the Solvent Evaporation Technique: II. Some Process Parameters Influencing the Preparation and Properties of Microspheres, Journal of Microencapsulation, 4(4), 289-297 (1987).

4. R. Bodmeier, J.W. McGinity: The Preparation and Evaluation of Drug-Containing Poly(dl-lactide) Microspheres Formed by the Solvent Evaporation Method, Pharmaceutical Research, 4(6), 465-471 (1987).

5. R. Bodmeier , J.W. McGinity: Solvent Selection in the Preparation of Poly(dl-lactide) Microspheres Prepared by the Solvent Evaporation Method, International Journal of Pharmaceutics, 43, 179-186 (1988).

6. R. Bodmeier, J.W. McGinity: Polylactic Acid Microspheres Containing Quinidine Base and Quinidine Sulfate Prepared by the Solvent Evaporation Technique: III. Morphology of the Microspheres during Dissolution Studies, Journal of Microencapsulation, 5(4), 325-330 (1988).

7. R. Bodmeier, H. Chen: Preparation of Biodegradable Poly(dl-lactide) Microparticles Using a Spray-Drying Technique, Journal of Pharmacy and Pharmacology, 40(11), 754-757 (1988).

8. R. Bodmeier, K.H. Oh, H. Chen: The Effect of the Addition of Low Molecular Weight Poly(dl-lactide) on Drug Release from Biodegradable Poly(dl-lactide) Drug Delivery Systems, International Journal of Pharmaceutics, 51(1), 1-8 (1989).

9. R. Bodmeier, H. Chen, O. Paeratakul: A Novel Approach to the Oral Delivery of Micro- and Nanoparticles, Pharmaceutical Research, 6(5), 413-417 (1989).

10. R. Bodmeier, O. Paeratakul: Evaluation of Drug-Containing Polymer Films Prepared from Aqueous Latexes, Pharmaceutical Research, 6(8), 723-728 (1989).

11. R. Bodmeier, K.H. Oh, Y. Pramar: Preparation and Evaluation of Chitosan Beads, Drug Development and Industrial Pharmacy, 15(9), 1475-1494 (1989).

12. R. Bodmeier , H. Chen: Evaluation of Biodegradable Poly(lactide) Pellets Prepared by Direct Compression, Journal of Pharmaceutical Sciences, 78(10), 819-822 (1989).

13. R. Bodmeier, O. Paeratakul: Spherical Agglomerates of Water-Insoluble Drugs, Journal of Pharmaceutical Sciences, 78(11), 964-967 (1989).

14. R. Bodmeier, H. Chen: Preparation and Characterization of Microspheres Containing the Anti-Inflammatory Agents, Indomethacin, Ibuprofen, and Ketoprofen, Journal of Controlled Release, 10, 167-175 (1989).

15. R. Bodmeier, O. Paeratakul: Drug Release from Laminated Polymeric Films Prepared from Aqueous Latexes, Journal of Pharmaceutical Sciences, 79(1), 32-36 (1990).

16. R. Bodmeier, O. Paeratakul: Propranolol HCl Release from Acrylic Films Prepared from Aqueous Latexes, International Journal of Pharmaceutics, 59, 197-204 (1990).

17. R. Bodmeier, H. Chen: Indomethacin Polymeric Nanosuspensions Prepared by Microfluidization, Journal of Controlled Release, 12, 223-233 (1990).

18. R. Alex, R. Bodmeier: Encapsulation of Water-Soluble Drugs by a Modified Solvent Evaporation Method: I. Effect of Process and Formulation Variables on the Drug Entrapment, Journal of Microencapsulation, 7(3), 347-355 (1990).

19. R. Bodmeier, O. Paeratakul, H. Chen, W. Zhang: Formation of Sustained Release Wax Matrices within Hard Gelatin Capsules in a Fluidized Bed System, Drug Development and Industrial Pharmacy, 16(9), 1505-1519 (1990).

20. R. Bodmeier, O. Paeratakul: Theophylline Tablets Coated with Aqueous Latexes Containing Dispersed Pore-Formers, Journal of Pharmaceutical Sciences, 79(10), 925-928 (1990).

21. R. Bodmeier, H. Chen, P. Tyle, P. Jarosz: Pseudoephedrine HCl Microspheres Formulated into an Oral Suspension Dosage Form, Journal of Controlled Release, 15, 65-77 (1991).

22. R. Bodmeier, O. Paeratakul: Zero-Order Potassium Chloride Release from Microporous Membrane-Coated Tablets Prepared with Aqueous Colloidal Polymer Dispersions, Pharmaceutical Research, 8(3), 355-359 (1991).

23. R. Bodmeier, O. Paeratakul: Determination of Plasticizers Commonly Used in Pharmaceutical Dosage Forms by High Performance Liquid Chromatography, Journal of Liquid Chromatography, 14(2), 365-375 (1991).

24. R. Bodmeier, O. Paeratakul: Process and Formulation Variables Affecting the Drug Release from Chlorpheniramine Maleate Beads Coated with Commercial and Self-Prepared Ethyl Cellulose Pseudolatexes, International Journal of Pharmaceutics, 70, 59-68 (1991).

25. R. Bodmeier, H. Chen, P. Tyle, P. Jarosz: Spontaneous Formation of Drug-Containing Acrylic Nanoparticles, Journal of Microencapsulation, 8(2), 161-170 (1991).

26. R. Bodmeier, H. Chen: Determination of the Acidic Degradation Products, Acetic, Propionic, Butyric, and Phthalic Acid in Aqueous Pseudolatexes of Cellulosic Ester by High Performance Liquid Chromatography, Drug Development and Industrial Pharmacy, 17(13) 1811-1822 (1991).

27. R. Bodmeier, O. Paeratakul: A Novel Multiple-Unit Sustained Release Indomethacin-Hydroxypropyl Methylcellulose Delivery System Prepared by Ionotropic Gelation of Sodium Alginate at Elevated Temperatures, Carbohydrate Polymers, 16, 399-408 (1991).

28. R. Bodmeier, J. Wang, H. Bhagwatwar: Process and Formulation Variables in the Preparation of Wax Microparticles by a Melt Dispersion Technique. I. Oil-in-Water for Water-Insoluble Drugs, Journal of Microencapsulation, 9(1), 89-98 (1992).

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30. R. Bodmeier, O. Paeratakul: Leaching of Water-Soluble Plasticizers from Polymeric Films Prepared from Aqueous Colloidal Polymer Dispersions, Drug Development and Industrial Pharmacy, 18(17), 1865 (1992).

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32. D.J. Dixon, K.P. Johnston, R.A. Bodmeier: Polymeric Materials Formed by Precipitation with a Compressed Antisolvent, AICHE Journal, 39(1) 127 -139 (1993).

33. R. Bodmeier, J. Wang: Microencapsulation of Drugs with Aqueous Colloidal Polymer Dispersions, Journal of Pharmaceutical Sciences, 82(2) 191-194 (1993).

34. R. Bodmeier, O. Paeratakul: Dry and Wet Strength of Polymeric Films Prepared from an Aqueous Colloidal Polymer Dispersion, Eudragit RS30D, International Journal of Pharmaceutics, 96 129-138 (1993).

35. R. Bodmeier, O. Paeratakul: The Effect of Curing on Drug Release and Morphological Properties of Ethyl Cellulose Pseudolatex-Coated Beads, Drug Development and Industrial Pharmacy, 20(9) 1517-1533 (1994).

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273. K. Johannsen, R. Bodmeier: Controlled Delivery of Bovine Serum Albumin from Alginate-Poloxamer-Based Microparticles. 31st Annual Meeting and Exposition of the Controlled Release Society, Honolulu, USA, #663, (2004).

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Release and Film Properties. 31st Annual Meeting and Exposition of the Controlled Release Society, Honolulu, USA, #440, (2004).

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286. D. Sticha, R. Bodmeier: In Vivo Performance Of Sprayable Formulations For Buccal Application. 2004 AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Baltimore, USA, Vol. 6, Abstract W4304 (2004).

287. K. Johannsen, J. Siepmann, R. Bodmeier: Alginate-poloxamer Microparticles For Time-controlled Pulmonary Delivery Of Proteins. 2004 AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Baltimore, USA, Vol. 6, Abstract W4028 (2004).

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290. I. Terebesi, W. Stark, R. Bodmeier: Extended release pellets prepared by dry polymer powder coating. 2005 the Pharmaceutical Sciences Fair & Exhibition, Nice, France, Abstract PO-242 (2005).

291. D. Sticha, R. Bodmeier: Influence of autoclaving and ultrasound physical properties of natural polymers. 2005 the Pharmaceutical Sciences Fair & Exhibition, Nice, France, Abstract PO-257 (2005).

292. D. Sticha, R. Bodmeier: Preparation and evaluation of powder formulations for buccal drug delivery. 2005 the Pharmaceutical Sciences Fair & Exhibition, Nice, France, Abstract SC-58 (2005).

293. S. Sungthongjeen, S. Puttipipatkhachorn, O. Paeratakul, A. Dashevsky, R. Bodmeier: Effect of Coating Formulations on Properties of Free Films and Rupturable Pulsatile Release Tablets. 32nd Annual Meeting & Exposition of the Controlled Release Society, Miami Beach, USA, #124 (2005).

294. M. Körber, R. Bodmeier: Investigation of protein solubility in PLGA solutions in ternary solvent mixtures. 32nd Annual Meeting & Exposition of the Controlled Release Society, Miami Beach, USA, #437 (2005).

295. X. Luan, R. Bodmeier: In situ forming microparticles (ISM) for 120-day controlled delivery of leuprolide acetate. 32nd Annual Meeting & Exposition of the Controlled Release Society, Miami Beach, USA, #440 (2005).

296. X. Luan, R. Bodmeier: Effect of poly(lactide-co-glycolide) (PLGA) type on the drug release from microparticles and in situ forming microparticles (ISM). 32nd Annual Meeting & Exposition of the Controlled Release Society, Miami Beach, USA, #441 (2005).

297. S. Sungthongjeen, O. Paeratakul, S. Limmatvapirat, S. Puttipipatkhachorn, R. Bodmeier: Multiple-Unit Floating Drug Delivery System Based on Gas Formation Technique. 32nd Annual Meeting & Exposition of the Controlled Release Society, Miami Beach, USA, #490 (2005).

298. A. Mohamad, A. Dashevsky, R. Bodmeier: Evaluation of microcrystalline cellulose (MCC) cores for modified release multiparticulates. 32nd Annual Meeting & Exposition of the Controlled Release Society, Miami Beach, USA, #493 (2005).

299. S. Jaraswekin, S. Prakongpan, R. Bodmeier: Comparison of the O/W- and O/O-Solvent Evaporation Method on the Release Behavior of Dexamethasone SodiumPhosphate-Loaded PLGA Microparticles. 32nd Annual Meeting & Exposition of the Controlled Release Society, Miami Beach, USA, #504 (2005).

300. F. Lecomte, V. Le Brun, J. Siepmann, R. Bodmeier: Plasticizing Effects of Drugs in Polymeric Systems: A Quantitative Treatment. 32nd Annual Meeting & Exposition of the Controlled Release Society, Miami Beach, USA, #740 (2005).

301. C. Curbach, R. Bodmeier: Comparison of Spray-Congealing and Melt Dispersion Techniques for the Preparation of Lipid Microparticles. 2005 AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Nashville, USA, #M1198 (2005).

302. V. Hoffart, M. Körber, R. MacRae, M Walther, R. Bodmeier: Effects of Unconventional Curing Conditions on Storage Stability of Pellets Coated with Aquacoat® ECD. 2005 AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Nashville, USA, #T3241 (2005).

303. H. Friedrich, A. Nada, R. Bodmeier: Formulations of Nifedipine Fast-Release Tablets. 2005 AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Nashville, USA, #W5132 (2005).

304. K. Möbus, J. Siepmann, R. Bodmeier: Glycerol Monooleate-Based Dry Powder Systems for the Controlled Release of Proteins. 2005 AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Nashville, USA, #W4059 (2005).

305. I. Terebesi, R. Bodmeier: Pre-Plasticized vs. Simultaneoulsy Platicized Ethylcellulose Powder for Dry Polymer Powder Coating. 2005 AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Nashville, USA, #M1239 (2005).

306. V. Hoffart, M. Körber, R. MacRae, M. Walther, R. Bodmeier: Storage Stability of Pellets Coated with the Aqueous Ethylcellulose Dispersion – Aquacoat® ECD at Elevated Temperature and Humidity. 2005 AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Nashville, USA, #T3240 (2005).

ORAL PRESENTATIONS (invited speaker)

1. Biodegradable microspheres prepared by the solvent evaporation method, College of Pharmacy, Oregon State University, Corvallis, USA, February 1986.

2. Preparation and evaluation of poly(lactide) microspheres, College of Pharmacy, University of North Carolina, Chapel Hill, USA, February 1986.

3. Biodegradable microspheres, Eli Lilly, Indianapolis, USA, April 1987.

4. Biodegradierbare Arzneistoffsysteme zur parenteralen Wirkstoffretardierung, Ludwig-Maximilians-Universität, Munich, Germany, August 1987.

5. Potential biodegradable delivery systems for peptides, Ferring Pharmaceuticals, Malmö, Sweden, September 1987.

6. The use of poly(lactides) in controlled drug delivery systems, The Upjohn Company, Kalamazoo, USA, November 1988.

7. Pharmaceutical applications of aqueous colloidal polymer dispersions, Membrane Science Colloquium, The University of Kentucky, Lexington, USA, April 1989.

8. Preparation and evaluation of poly(lactide) microparticles and pellets, American Association of Pharmaceutical Scientists, AAPS, Midwest Regional Meeting, Chicago, USA, May 1989.

9. Aqueous latexes in the preparation of polymeric films and nanoparticles, The Upjohn Company, Kalamazoo, USA, August 1989.

10. Controlled release oral suspensions, Dorsey Laboratories, Lincoln, USA, August 1989.

11. Aqueous latexes in controlled drug delivery, American Association of Pharmaceutical Scientists, AAPS, Western Regional Meeting, Reno, USA, February 1990.

12. Pharmazeutische Anwendungen von wäßrigen Latexes, Christian-Albrechts-Universität, Kiel, Germany, March 1990.

13. Characterization of cephalosporin-containing microspheres for intramammary injection, The Upjohn Company, Kalamazoo, USA, May 1990.

14. Film-coating of solid dosage forms with aqueous latexes, Marion Merrel Dow, Kansas City, USA, July 1990.

15. Drug-containing nanoparticles and aqueous latexes prepared by microfluidization-solvent evaporation methods, Pre-World Congress on Particle Technology, Gifu, Japan, September 1990.

16. Wax and polymer microspheres prepared by emulsification techniques, 24th Gattefosse Meeting, Saint-Rémy, France, September 1990.

17. Process and formulation variables in latex coating, Parke-Davis, Morris Plains, USA, Oktober 1990.

18. Novel microencapsulation techniques, Burroughs Wellcome, Greenville, USA, February 1991.

19. Oral controlled release drug delivery systems, North Carolina Pharmaceutical Discussion Group, Chapel Hill, USA, February 1991.

20. Sustained release polymeric delivery systems, Genentech, San Francisco, USA, February 1991.

21. Controlled release drug delivery systems, SmithKline Beecham, Parsippany, USA February 1991.

22. Pharmazeutische Anwendungen wäßriger Polymerdispersionen, Universität des Saarlandes, Saarbrücken, Germany, April 1991.

23. Pharmazeutische Anwendungen wäßriger Polymerdispersionen, Universität Regensburg, Regensburg, Germany, May 1991.

24. Pharmazeutische Anwendungen wäßriger Polymerdispersionen, Ludwig-Maximilians-Universität München, Munich, Germany, May 1991.

25. Microencapsulation workshop, The Upjohn Company, Kalamazoo, USA, September, 1991.

26. Spray-drying of pharmaceuticals, American Association of Pharmaceutical Scientists, AAPS, Western Regional Meeting, Reno, USA, March 1992.

27. Formulation and process variables affecting the coating with aqueous polymer dispersions, PharmTech Conference, New Jersey, USA, September 1991.

28. Wäßrige kolloidale Polymerdispersionen in modernen Arzneiformen, Albert-Ludwigs-Universität, Freiburg, Germany, April 1992.

29. Moderne Mikroverkapselungsverfahren, Freie Universität Berlin, Berlin, Germany, June 1992.

30. Untersuchungen von wäßrigen kolloidalen Polymerdispersionen und multipartikulären Arzneiformen, Universität Regensburg, Regensburg, Germany, January 1993.

31. Polymeric and lipophilic microspheres, SmithKline Beecham, New Jersey, USA, March 1993.

32. Microencapsulation workshop, Cima Labs, Minneapolis, USA, June 1993.

33. Sustained release microparticles: Preparation and evaluation, First International Conference on Pharmaceutical and Food Sciences and Technology, New Jersey, USA, August 1993.

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35. Polymeric microparticles prepared by solvent-evaporation and spray-drying techniques, 3rd European Symposium on Controlled Drug Delivery, Noordwijk, The Netherlands, April 1994.

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38. Novel microencapsulation techniques, SmithKline Beecham, Weybridge, England, February 1995.

39. Drug release from coated dosage forms, Symposium on Coating Technology, Röhm Pharma, Darmstadt, Germany, April 1995.

40. Arzneiformen im Spiegel der Arzneitherapie - neuere Entwicklungen bei Parenteralia, XXXIII. Internationaler Fortbildungskurs - Pharmacon, Meran, Italy, May 1995.

41. Perorale Arzneiformen: Neues über bekannte galenische Darreichungsformen, Pharmazeutische Gesellschaft Bayern, Munich, Germany, June 1995.

42. Mechanical properties of polymeric coatings- implications for drug release, Pfizer, Groton, USA, September 1995.

43. Polymeric microparticles prepared without organic solvents, 10th International Symposium on Microencapsulation, Austin, USA, September 1995.

44. Microencapsulation workshop, College of Pharmacy, The University of Texas at Austin, Austin, USA, February 1996.

45. Neue Entwicklungen bei peroralen Retardarzneiformen, Festvortrag zur Eröffnung des Galenik-Labors, L.A.B., Ulm, Germany, March 1996.

46. Biodegradable microparticles, Isis Pharmaceuticals, San Diego, USA, May 1996.

47. Microparticles for ocular delivery, Alcon Laboratories, Ft. Worth, USA, May 1996.

48. Pharmazeutisch-technologische Anwendungen wäßriger Polymerdispersion, Martin-Luther-Universität, Halle, Germany, June 1996.

49. Microencapsulation workshop, Erasmus-Workshop, Faculté de Pharmacie, Université Henri Poincare - Nancy, Frankreich, June 1996.

50. Acrylic and cellulosic polymers used in the coating of solid dosage forms, Prographarm, Paris, France, September 1996.

51. Polymeric microparticles prepared without organic solvents, Microencapsulation Mini-Symposium, St. Petersburg, Russia, September 1996.

52. Entwicklung neuer wäßriger Polymerdispersionen zum Überziehen fester Arzneiformen, BASF, Ludwigshafen, Germany, January 1997.

53. Technological Approaches for rational drug delivery, 1st Congress of Pharmaceutical Sciences, Ribeirao Preto, Sao Paulo, Brasil, April 1997.

54. Cubic Phase Drug Delivery Systems, Local Chapter Meeting of the Controlled Release Society, Chulalongkorn University, Bangkok, Thailand, August 1997.

55. Drug Release from Coated Pellets, Post-Symposium Workshop, 11th International Symposium on Microencapsulation, Bangkok, Thailand, August 1997.

56. Formulation and process variables affecting the drug release from coated dosage forms, Symposium on Particulate Systems from Formulation to Production, Istanbul, Turkey, Oktober 1997.

57. Arzneistofffreisetzung aus überzogenen Pellets, APV (Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik) - Kurs über „Angewandte Systeme zur gesteuerten Wirkstofffreigabe", Nürnberg, Germany, December 1997.

58. Microparticulate and pulsatile drug delivery systems, Lilly Research Laboratories, Indianapolis, USA, March 1998.

59. Polymere Retard-Arzneiformen zur parenteralen und peroralen Anwendung, Ludwig-Maximilians Universität München, Munich, Germany, April 1998.

60. Pulsatile drug delivery systems, Skye Pharma, Basel, Switzerland, April 1998.

61. Process and formulation variables affecting the drug release from coated pellets, Janssen Pharmaceutica, Belgium, May 1998.

62. Pulsatile drug delivery systems, Workshop, Smith Kline Beecham, London, England May 1998.

63. Formulation and process variables affecting the release from coated dosage forms, Röhm Pharma Symposium, London, England, June 1998.

64. Curing of coated pellets, Glatt-Symposium, Heidelberg, Germany, October 1998.

65. In-situ microparticle technology, Atrix Labs, Ft. Collins, USA, February 1999.

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67. Pulsatile drug delivery systems, Novartis, Basel, Switzerland, May 1999.

68. Microparticles formed by the solvent evaporation method, Elan Pharmaceuticals, Dublin, Ireland, May 1999.

69. Fast disintegrating drug delivery systems with increased residence time, Pasteur Merieux Connaught, Lyon, France, July, 1999.

70. In-situ microparticle technology, Pasteur Merieux Connaught, Lyon, France, July 1999.

71. In-situ formation of biodegradable microparticles, 12th International Symposium on Microencapsulation, London, England, September 1999.

72. Film coating of gelatin capsules, APV-workshop, Amsterdam, The Netherlands December 1999.

73. Coating with Kollicoat SR 30D, BASF Symposium Pharma, Paris, France, March 2000.

74. In situ forming biodegradable microparticles, Faculty of Pharmacy, Mahidol University, Bangkok, Thailand, March 2000.

75. Biodegradable drug delivery systems, Bayer AG, Leverkusen, Germany, March 2000.

76. Preparation techniques for biodegradable microparticles, AAPS Annual Meeting, Indianapolis, USA, November 2000.

77. Cellulosic polymers for coating, APGI Symposium on "New trends in polymers for oral and parenteral administration", Paris, France, March 2001.

78. Bioabbaubare Arzneiformen zur parenteralen Applikation, College of Pharmacy, Universität Wien, Austria, May 2001.

79. In-situ forming biodegradable drug delivery systems, School of Pharmacy, University of Colorado, USA, July 2001.

80. In-situ forming biodegradable drug delivery systems, British Pharmaceutical Conference, Royal Pharmaceutical Society of Great Britain, Glasgow, Scotland, September 2001.

81. In-situ forming biodegradable drug delivery systems, College of Pharmacy, Philipps-Universität, Marburg, Germany, November 2001.

82. Peroral pulsatile drug delivery systems, Faculty of Pharmacy, Mahidol University, Bangkok, Thailand, March 2002.

83. In-situ forming biodegradable drug delivery systems, PharmaciaUpjohn, Milano, Italy, May 2002.

84. In-situ forming biodegradable drug delivery systems, American Chemical Society (ACS) Prospectives Conference Series on Future Directions of Drug Delivery Technologies: Molecular Design, Cellular Response and Nanotechnology, Boston, USA, October 2002.

85. Coating – Extended release formulations, BASF-Laborseminar, Ludwigshafen, Germany, June 2003.

86. Carrier/coating materials and processes used for extended release dosage forms, 43rd AFI Symposium, Perugia, Italy, June 2003.

87. Overview of current materials/polymers utilised in solid MR forms, 30th Annual Meeting of the Controlled Release Society, Workshop on Modified Release Products and Challenges in Oral Delivery, Glasgow, Scotland, July 2003.

88. Coating materials used in extended release formulations, Royal Golden Jubilee Series XXIV: Pharmaceutics and Pharmaceutical Technology, Mahidol University, Bangkok, Thailand, October 2003.

89. Recent Advances in Film Coating, 2004 AAPS Annual Meeting and Exposition, American Association of Pharmaceutical Scientists, Baltimore, USA, Vol. 6, (2004).

PH.D. - GRADUATED
The University of Texas at Austin

Name	First Name	Country	Title - Dissertation	Year
Paeratakul	Ornlaksana	Thailand	Pharmaceutical Applications of Aqueous Colloidal Polymer Dispersions	1993
Wong	David	Hongkong	Water-Soluble Polymers in Pharmaceutical Aqueous Colloidal Polymer Dispersions	1994
Chang	Chin-Ming	Taiwan	Application of Monoglyceride-Based Materials as Sustained-Release Drug Carriers	1995
Kositprapa	Unchalee	Thailand	Characterization and Preparation of Drug Complexes and their Delivery Systems	1996
Sriwongjanya	Mongkol	Thailand	Pharmaceutical Applications of Ion Exchange Resins	1996
Guo	Xiaodi	China	Physicochemical and Mechanical Properties Influencing the Drug Release from Coated Dosage Forms	1996

M.S. - GRADUATED
The University of Texas at Austin

Name	First Name	Country	Title - Thesis	Year
Bhagwatwar	Harshal	India		
Chen	Huagang	China	Preparation and Characterization of Drug-Containing Microspheres and Nanoparticles for Controlled Drug Delivery	1992
Wang	Hui	China		

PH.D. - GRADUATED
(Freie Universität Berlin)

Name	First Name	Country	Title Dissertation	Year
Fischer-Carius	Andreas	Germany	Untersuchungen an extrudierten und sphäronisierten Matrixpellets mit retardierter Wirkstofffreigabe	1998
Krögel	Ina	Germany	Oral Drug Delivery Systems With Modified Release	1998
Hülsmann	Stefan	Germany	Verbesserung der Lösungsgeschwindigkeit eines schwer wasserlöslichen Arzneistoffs durch Schmelzextrusion	1999
Siepmann	Jürgen	Germany	Polymeric Controlled Drug Delivery Systems: Elucidation of Transport Mechanisms and Optimization of Release Patterns	1999
Wesseling	Martin	Germany	Preparation and Investigation of Coated Multiparticulate Drug Delivery Systems	1999
Kranz	Heiko	Germany	In Situ Forming Biodegradable Drug Delivery Systems	2000
Schmidt	Christoph	Germany	Muliparticulate Oral Drug Delivery Systems	2000
Gonzàlez Ferreiro	Maria	Spain	Delivery Systems for Antisense Oligonucleotides	2001
Seemann	Stefanie	Germany	Gasgefüllte Mikropartikel – ein neues nichtvirales Gentransfersystem	2001
Vázquez Lantes	Maria Cristina	Spain	Drug Delivery Systems With Controlled Drug Release	2001
Streubel	Alexander	Germany	Oral Delivery Systems with Modified Drug Release	2002
Wagner	Klaus	Germany	Aqueous Polymer Dispersions for Extended Release Dosage Forms	2002
Bussemer	Till	Germany	Oral Pulsatile Drug Delivery Systems	2003
El-Kharraz	Khaled	Lybia	Alternative Methods for Microencapsulation of Hydrophilic Drugs	2003
Im-Emsap	Wandee	Thailand	In Vitro and in vivo Properties of Injectable Biodegradable in situ Forming Microparticles Systems	2003
Pearnchob	Nantharat	Thailand	Evaluation of New Film Coating Processes and Materials	2003
Ahmed	Abid	Pakistan	Parenteral Controlled Release Delivery Systems for Antisense Oligonucleotide Drugs	2003
Werner	Ulrike	Germany	In Situ Gelling Nasal Inserts for Prolonged Drug Delivery	2003